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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,600	06/19/2006	Hiroaki Torii	W1878.0235	4554
32172	7590	01/13/2010	EXAMINER	
DICKSTEIN SHAPIRO LLP			LIN, JERRY	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/583,600	<b>Applicant(s)</b> TORII ET AL.	
	<b>Examiner</b> JERRY LIN	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species A, claims 2 and 26, drawn to where the number of actually measured peptide fragments derived from the target protein to be analyzed is zero.

Species B, claims 3-9, 15-21, 27-33, and 39, drawn to where the actually measured peptide fragments are contained in a fully length amino acid sequence of a known protein. (Subspecies election is required if this species is elected.)

Species C, claims 10-14, 22-25, and 34-38, drawn to where the actually measured peptide fragments are contained in a fully length amino acid sequence of a protein with predicted peptide fragments. (Subspecies election is required if this species is elected).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1 and 16.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Species A, B, and C each comprise of a different special technical feature. For example, Species A has the special technical feature where the number of actually measured peptide fragments derived from the target protein to be analyzed is zero, which Species B and C do not have. Species B has the special technical feature where the actually measured peptide fragments are contained in a fully length amino acid sequence of a known protein, which Species A and C do not have. Species C has the special technical feature where the actually measured peptide fragments are contained in a fully length amino acid sequence of a protein with predicted peptide fragments, which Species A and B do not have. Thus each of the species has its own special technical feature, which is not shared by the other species.

***Subspecies for Species B***

This species contains claims directed to more than one subspecies of the generic invention. These subspecies are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The subspecies are as follows:

Subspecies i, claims 4, 15, 28, and 39, drawn to where the post-translational modification is attributed to a modifying addition to a side chain of an amino acid residue present in the unidentified predicted peptide fragments.

Subspecies ii, claims 5, 17, and 29, drawn to where the post-translational processing of N-terminal truncation would occur to convert the known protein to a mature protein.

Subspecies iii, claims 6, 18, and 30, drawn to where the post-translational processing of C-terminal truncation would occur to convert the known protein to a C-terminally truncated protein.

Subspecies iv, claims 7, 19, and 31, drawn to where the splicing different from presumable RNA splicing in a plurality of exons contained in the genomic gene portions would occur.

Subspecies v, claims 8, 20, and 32, drawn to where protein splicing that removes a portion of an amino acid sequence would occur.

Subspecies vi, claims 9, 21, and 33, drawn to where one replacement of a translated amino acid attributed to single nucleotide polymorphism would occur in an exon contained in the genomic gene portions.

Applicant is required, in reply to this action, to elect a single subspecies to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected subspecies, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional subspecies which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1 and 16.

The subspecies listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the subspecies lack the same or corresponding special technical features for the following reasons:

Subspecies i-vi each comprise of a different special technical feature which is not shared by the other subspecies. Subspecies i, claims 4, 15, 28, and 39, has the special technical feature where the post-translational modification is attributed to a modifying addition to a side chain of an amino acid residue present in the unidentified predicted peptide fragments. Subspecies ii, claims 5, 17, and 29, has the special technical feature where the post-translational processing of N-terminal truncation would occur to convert the known protein to a mature protein. Subspecies iii, claims 6, 18, and 30, has the special technical feature where the post-translational processing of C-terminal

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truncation would occur to convert the known protein to a C-terminally truncated protein. Subspecies iv, claims 7, 19, and 31, has the special technical feature where the splicing different from presumable RNA splicing in a plurality of exons contained in the genomic gene portions would occur. Subspecies v, claims 8, 20, and 32, has the special technical feature where protein splicing that removes a portion of an amino acid sequence would occur. Subspecies vi, claims 9, 21, and 33, has the special technical feature where one replacement of a translated amino acid attributed to single nucleotide polymorphism would occur in an exon contained in the genomic gene portions. Thus each of the species has its own special technical feature, which is not shared by the other species.

### ***Subspecies for Species C***

This species contains claims directed to more than one subspecies of the generic invention. These subspecies are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The subspecies are as follows:

Subspecies aa, claims 11, 22, and 35, drawn to where the post-translational modification is attributed to a modifying addition to a side chain of an amino acid residue present in the unidentified predicted peptide fragments.

Subspecies bb, claims 12, 23, and 36, drawn to where the splicing different from presumable RNA splicing in a plurality of exons contained in the genomic gene portions would occur.

Subspecies cc, claims 13, 24, and 37, drawn to where protein splicing that removes a portion of an amino acid sequence would occur.

Subspecies dd, claims 14, 25, and 38, drawn to where one substitution of a translated amino acid attributed to single nucleotide polymorphism would occur in an exon contained in the genomic gene portions.

Applicant is required, in reply to this action, to elect a single subspecies to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected subspecies, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional subspecies which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1 and 16.

The subspecies listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the subspecies lack the same or corresponding special technical features for the following reasons:

Subspecies aa-dd each comprise of a different special technical feature which is not shared by the other subspecies. Subspecies aa, claims 11, 22, and 35, has the special technical feature where the post-translational modification is attributed to a



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modifying addition to a side chain of an amino acid residue present in the unidentified predicted peptide fragments. Subspecies bb, claims 12, 23, and 36, has the special technical feature where the splicing different from presumable RNA splicing in a plurality of exons contained in the genomic gene portions would occur. Subspecies cc, claims 13, 24, and 37, has the special technical feature protein splicing that removes a portion of an amino acid sequence would occur. Subspecies dd, claims 14, 25, and 38, has the special technical feature where one substitution of a translated amino acid attributed to single nucleotide polymorphism would occur in an exon contained in the genomic gene portions. Thus each of the species has its own special technical feature, which is not shared by the other species.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species and subspecies if required to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of a species and subspecies may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY LIN whose telephone number is (571)272-2561. The examiner can normally be reached on 7:30-6:00pm, M-TH.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Jerry Lin/

Primary Examiner, Art Unit 1631

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